

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION**

UNITED STATES OF AMERICA
ex rel. JON VITALE,

Plaintiff,

v.

MIMEDX GROUP, INC.

Defendant.

Civil Action No. 3:17-cv-00166-RBH

UNITED STATES' STATEMENT OF INTEREST

The United States respectfully submits this Statement of Interest, pursuant to 28 U.S.C. § 517, to respond to certain arguments made in Defendant MiMedx Group, Inc.'s ("MiMedx") Reply In Support of its Motion to Dismiss Relator's Complaint ("Reply"), Dkt. 67, and Memorandum of Law in Support of its Motion to Dismiss Relator's Complaint ("Motion to Dismiss"), Dkt. 65, and in Relator Jon Vitale's Opposition to Defendant's Motion to Dismiss ("Opposition"), Dkt. 66. Although the United States has not intervened in this action, it remains the real party in interest. *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 930 (2009). The False Claims Act ("FCA"), 31 U.S.C. §3729 *et seq.*, is the United States' primary tool to redress fraud on the government. Thus, the United States has a keen interest in the development and correct application of the law in this area. The United States takes no position on the applicability of the public disclosure

bar to Relator's complaint and likewise takes no position on whether Relator has sufficiently pleaded his allegations in light of Federal Rule of Civil Procedure ("FRCP") 9(b). Rather, to the extent that the court does not grant Defendant's motion on those grounds and an examination of Relator's Complaint in light of FRCP 12(b)(6) is necessary, the United States submits this brief for the limited purpose of addressing three points made in the parties' briefing relevant to that inquiry.

First, a drug manufacturer knowingly and willfully paying a Medicare patient to fill a Medicare-reimbursed prescription of the manufacturer's own product, either directly or indirectly and with an intent to induce that purchase, violates the Anti-Kickback Statute ("AKS"). That the United States Department of Health and Human Services, Office of the Inspector General ("HHS-OIG") has issued an advisory opinion to a non-profit entity seeking to provide copay assistance to federal patients, in which the agency agrees to refrain from administrative enforcement action against the non-profit so long as it follows certain safeguards, does not alter the elements of the AKS needed to establish a violation by a pharmaceutical manufacturer.

Second, that a patient who received such remuneration from a manufacturer to purchase the drug already had a prescription for it does not negate any elements of the AKS. The Statute prohibits providing illegal remuneration to induce the patient's actual purchase of a product, and not just a physician's referral of it.

Third, as the Third Circuit held in *United States ex rel. Greenfield v. Medco Health Solutions, Inc. et al.*, 880 F.3d 89 (3d Cir. 2018), once such an AKS violation has been shown, establishing a link between the violation and federally reimbursed claims is

sufficient to establish False Claims Act liability. A relator or government plaintiff need not show that the AKS violation was the “but for” cause of the submission of the claims at issue.

BACKGROUND

On January 19, 2017, Relator Jon Vitale (“Relator”) filed his *qui tam* Complaint in this matter under seal pursuant to the FCA. Dkt. 1. On August 8, 2019, after investigating relator’s allegations, the United States filed a Notice of Election to Decline Intervention in this matter. Dkt. 40. Relator served the Complaint on Defendant shortly thereafter, and on October 1, 2018, MiMedx filed its Motion to Dismiss. Dkt. 65. Relator filed his Opposition on October 15, 2018. Dkt. 66.

PATIENT COST OBLIGATIONS UNDER MEDICARE

When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a partial payment, which may take the form of a “copayment,” “coinsurance,” or “deductible” (collectively “copays”). These copay obligations may be substantial for expensive medications. For example, under Medicare Part B, which generally covers physician-administered medications (*e.g.*, drugs that must be injected or infused in a physician’s office), Congress determined that, in most circumstances, Medicare will pay 80 percent of the reasonable charge for the medication and the patient cost obligation will be 20 percent. *See, e.g.*, 42 U.S.C. § 1395l.

Under Medicare Part D, which typically covers prescription medications that patients may take at home (*e.g.*, oral medications), Congress determined that the standard Part D benefit must require copayments which vary throughout the year, depending upon

a beneficiary's total Part D covered expenses incurred that year up to that point. *See* 42 U.S.C. § 1395w-102. For example, after meeting an annual deductible (originally \$250 in 2006), the standard Part D benefit requires a 25 percent patient copay up to an initial coverage limit (originally \$2,250 in 2006). *Id.* at b(1)-(2). For costs incurred above an annual out-of-pocket threshold (originally \$3,600 in 2006), the standard Part D benefit requires a patient copay of 5 percent or a fixed dollar amount (originally \$5 for brand name drugs in 2006), whichever is greater, on costs for the remainder of the year. *Id.* at b(4).¹

The existence of patient copay obligations in federal healthcare programs encourages both physicians and beneficiaries to be efficient consumers of federally-reimbursed health care products, while also encouraging those manufacturing such products to price them responsibly. Manufacturers paying the Medicare copays of those seeking to buy their drug circumvent this congressionally designed check on health care costs. As the United States Department of Health and Human Services, Office of the Inspector General (“HHS-OIG”) has observed, drug manufacturers paying the Medicare Part D copays of patients taking their products “shield beneficiaries from the economic effects of drug pricing, [and] thus eliminate a market safeguard against inflated prices.” HHS-OIG, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70625 (Nov. 22, 2005) (“2005 SAB”).

¹ Patient copay obligations in the “coverage gap” between the initial coverage limit and the annual out of pocket threshold amount may vary depending upon whether the product is a brand name or generic drug. *See* 42 U.S.C. § 1395w-102(b)(2)(D). The financial thresholds for the deductible, initial coverage limit, and annual out of pocket threshold have increased each year since 2006, pursuant to a statutory and regulatory formula.

ARGUMENT

To the extent the Court does not grant Defendant’s motion on the basis of FRCP 9(b) or the public disclosure bar, and an assessment of Relator’s allegations in the context of FRCP 12(b)(6) is necessary, the United States, as the real party in interest, submits this statement of interest to address three issues.

I. A Manufacturer Knowingly and Willfully Paying a Medicare Patient’s Copay, Directly or Indirectly and With an Intent to Induce a Medicare-Reimbursed Purchase of the Manufacturer’s Product, Violates the AKS.

A manufacturer that knowingly and willfully pays a Medicare patient to fill a Medicare-reimbursed prescription of its own product, directly or indirectly with an intent to induce the patient to complete that purchase, violates the AKS. The AKS, 42 U.S.C. § 1320a-7b(b)(2)(B), prohibits “knowingly and willfully offer[ing] or pay[ing] any remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.”² *Id.* The AKS specifies that remuneration includes anything of value, including “cash” and “in kind” payments or

² Congress adopted the AKS to “strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the medicare and medicaid programs.” H.R. Rep. No. 95-393, at 1 (1977). Congress considered the cost implications to federal healthcare programs when determining what conduct to prohibit and determined that the inducements it did prohibit would “contribute significantly to the cost” of federal healthcare programs, absent federal penalties as a deterrent. H.R. Rep. No. 95-393 at 53 (1977), as reprinted in 1977 U.S.C.C.A.N. 3039, 3056.

rebates. *Id.* Accordingly, money and other forms of financial subsidies that can be used to pay or waive Medicare copays constitutes remuneration under the AKS.

Consequentially, courts have found allegations that a defendant knowingly and willfully provided such remuneration, with an intent to induce patients to purchase Medicare-reimbursed products or services, to properly allege an AKS violation. *See, e.g., United States ex rel. Lutz v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 498-99, 501 (D.S.C. 2016) (holding that the government’s complaint alleging waivers of federal copays and deductibles adequately states a False Claims Act claim predicated upon AKS violations); *United States ex rel. Riedel v. Boston Heart Diagnostic Corp.*, --- F. Supp.3d ---, 2018 WL 4354944, at *9-10 (D.D.C. Sept. 12, 2018) (“[T]he Court finds that the relator sufficiently alleges that Boston Heart's waiver of patients’ co-payments and deductibles constitutes a kickback[.]”). It is not a defense to AKS liability that the defendant paid such remuneration through an intermediary, rather than directly, because the Statute prohibits “indirectly” or “covertly” offering such remuneration. 42 U.S.C. § 1320a-7b(b)(2)(B).

Nonetheless, Defendant incorrectly seems to suggest that HHS-OIG is unconcerned with the AKS implications of pharmaceutical manufacturers paying their own patients’ Medicare copays so long as the payment is through an intermediary foundation. By its plain terms, however, the AKS not only prohibits pharmaceutical companies from “directly” paying Medicare copays to induce purchases of their products, the statute also prohibits them from using intermediaries to accomplish the same goal “indirectly.” *Id*; *see also*, 2005 SAB at 70626 (“[I]f a manufacturer of a drug covered under Part D were to subsidize cost-sharing amounts (*directly or indirectly through a [Patient Assistance*

Program]) incurred by Part D beneficiaries for the manufacturer’s product . . . such subsidies would be squarely prohibited by the statute . . . [and] present all the usual risks of fraud and abuse associated with kickbacks[.]”) (emphasis added). HHS-OIG has never approved a proposed arrangement where a pharmaceutical company would use a foundation to pay its own patient’s copays in this manner. *Id.*; *see also* HHS-OIG Adv. Op. No. 02-13 (Oct. 4, 2002) (declining to agree to forego enforcement action where a pharmaceutical manufacturer proposed to establish a non-profit to provide copay assistance to patients taking its product).

Contrary to Defendant’s suggestion, the fact that HHS-OIG has issued advisory opinions to certain 501(c)(3) entities—agreeing to forego enforcement where a foundation provides *bona-fide*, independent financial assistance to federal patients and, meets certain strict safeguards—confirms HHS-OIG’s concern about such payments. For example, Patient Access Network Foundation (“PANF”) submitted an application to HHS-OIG and certified many facts about the nature of its operations and detailed safeguards that it agreed to follow in operating its copay assistance funds. *See*, HHS-OIG Adv. Op. No. 07-18 (Dec. 19, 2007). HHS-OIG concluded that, although PANF’s proposal “could potentially generate prohibited remuneration under the [AKS], if the requisite intent to induce or reward referrals of Federal health care program business were present,” it would agree to refrain from imposing administrative sanctions against PANF *only* if PANF abided by the

conditions and safeguards that it certified to be true. HHS-OIG Adv. Op. No. 07-18 at 9, 14.³

Defendant makes two arguments relating to PANF's HHS-OIG advisory opinion. First, it suggests that one must plead that there was non-compliance with the advisory opinion to allege an AKS violation. Second, Defendant appears to argue that, so long as PANF itself has not violated its advisory opinion, there can be no AKS liability for MiMedx, regardless of MiMedx's conduct or intent. *See, e.g.*, Dkt. 67 at 8-10.

First, as Relator correctly observes, *see* Dkt. 66 at 13, the specifics of the HHS-OIG advisory opinions issued to 501(c)(3) foundations and other guidance do not alter the elements of the AKS or represent an exhaustive list of considerations of AKS liability as to MiMedx. Accordingly, and contrary to MiMedx's suggestion, they do not create new conditions, the non-compliance with which must be specifically pled to sufficiently allege an AKS violation by MiMedx. Rather, they represent the conditions under which HHS-OIG agreed to refrain from certain administrative enforcement action against PANF, despite the fact that PANF's conduct at issue would violate the AKS if the requisite intent were present.

Although a well-pled complaint against a pharmaceutical manufacturer may include allegations that show that the defendant's conduct ran contrary to the types of safeguards described in an HHS-OIG advisory opinion to a 501(c)(3) foundation, it is not necessary

³ PANF made additional certifications and modified its advisory opinion in 2015. *See* Notice of Modification of HHS-OIG Adv. Op. No. 07-18 (Oct. 26, 2015).

and certainly not the only way to plead an AKS violation against the manufacturer arising from the payment of patient copays. The ultimate analysis with respect to MiMedx's conduct must therefore focus on the AKS elements themselves.⁴ Put another way, the extent to which Relator has succeeded or failed in pleading an AKS violation here cannot be determined by comparing Relator's allegations against MiMedx to an advisory opinion that does not apply to MiMedx. It must be determined based upon whether Relator has sufficiently pled that MiMedx knowingly and willfully provided remuneration to patients, directly or indirectly, covertly or overtly, with an intent to induce their purchases of federally-reimbursed health care services or products. 42 U.S.C. § 1320a-7b(b)(2)(B).

Second, the advisory opinion to PANF states on its face that it does not afford any entity other than PANF any protection, and that, even as to PANF, it does not apply to conduct outside the scope of PANF's certifications to HHS-OIG. *See* HHS-OIG Adv. Op. No. 07-18 at *15. Even absent this express limitation, PANF's compliance with its own advisory opinion would not shield MiMedx from potential AKS liability. HHS-OIG has made clear that its advisory opinions to charitable foundations have not considered or opined on the conduct of their donors. HHS-OIG, Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120, 31123 (May 30, 2014) ("2014 SAB") ("[W]hen we have issued favorable advisory opinions

⁴ By the same token, if an entity that was not the recipient of an HHS-OIG advisory opinion nevertheless strictly adheres to the letter and spirit of the safeguards in an existing advisory opinion, that might provide the entity with a basis to assert that it did not possess the requisite intent to violate the AKS. Such an inquiry would involve a fact-specific, case-by-case determination.

regarding Independent Charity PAPs, the focus has been on the charities that requested the opinions—not the donors.”). Given the differences between foundations and pharmaceutical companies (*e.g.* foundations do not have a sales force marketing specific products and do not generate revenue from the purchase of products reimbursed by Medicare) the safeguards under which HHS-OIG agreed to forego administrative enforcement action against PANF may not be sufficient to address the AKS implications of a pharmaceutical company paying its own patients’ copays through PANF.

II. That a Patient May Already Have Been Prescribed A MiMedx Product Does Not Mean That MiMedx Cannot Have Knowingly and Willfully Provided Remuneration With an Intent to Induce The Patient to Purchase the Product.

Defendant’s argument that there can be no AKS liability for knowingly and willfully paying a patient’s Medicare copay because the patient may have already been prescribed the medication ignores that the AKS prohibits providing such remuneration with an intent to induce a person to *purchase* the medication, and not just to *prescribe* or *refer* it. As discussed above, the AKS, 42 U.S.C. § 1320a-7b(b)(2)(B), prohibits “knowingly and willfully offer[ing] or pay[ing] any remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . *to purchase* . . . any good . . . for which payment may be made in whole or in part under a Federal health care program.” *Id.* (emphasis added). This prohibition is separate from the AKS’s other

prohibition of providing such remuneration to induce a referral or recommendation (*e.g.*, a prescription) that subsequently leads to the purchase of a good or service.⁵

If MiMedx's argument were taken to its logical conclusion, manufacturers could simply pay the Medicare copays of their patients so long as the patients already had a prescription. Such a result would effectively eliminate the statutory Medicare copay requirements for, among other things, prescription drugs, *see e.g.*, 42 U.S.C. § 1395w-102, and would remove the check on the system that Congress designed to encourage beneficiaries to be efficient consumers of federally-reimbursed health care products, while also encouraging those manufacturing such products to price them responsibly. Such a subversion of Congress's design of the Medicare program, *see, e.g.*, 42 U.S.C. §§ 1395l, 1395w-102, would also run counter to the AKS's clear prohibition on offering money to induce a purchase of a product or service reimbursed by a Federal health insurance program. *See* 42 U.S.C. § 1320a-7b(b)(2)(B).

III. Upon Showing an AKS Violation, Establishing a Link Between The AKS Violation and a Claim to Medicare Is Sufficient to Establish False Claims Act Liability.

Upon showing an AKS violation against a defendant, establishing a link between the AKS violation and a claim submitted to Medicare is sufficient to establish a False Claims Act violation. To the extent either Relator or Defendant suggests that the Relator

⁵ The AKS also prohibits offering such remuneration to induce a person to “to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.” 42 U.S.C. § 1320a-7b(b)(2)(A).

must prove that the AKS violation actually “caused” a claim to be submitted that would not otherwise have been submitted, *see* Dkt. 65 at 14-15; Dkt. 66 at 16, that is incorrect as a matter of law. *See United States ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 96 (3d Cir. 2018) (rejecting defendant’s argument that FCA liability predicated on an AKS violation “requires proof the harm would not have occurred in the absence of—that is, but for, the defendant’s conduct”); *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-cv-10601, 2018 WL 1996829, at *3, (D. Mass Apr. 27, 2018) (“Relators need not show that a quid pro quo exchange occurred, or that the physicians would not have prescribed Defendant’s medication but for the kickbacks.”); *United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 330-32 (S.D.N.Y. 2014) (rejecting argument that post-2010 AKS requires “but for” causation).

The Third Circuit in *Medco* recently rejected similar arguments and held that, to establish FCA liability predicated on a violation of the AKS, a plaintiff is not required to show that a kickback actually influenced a patient or physician’s decision to use a particular provider or service, or otherwise actually caused the claim to be submitted. 880 F. 3d. at 97; *see also Bawduniak*, 2018 WL 1996829 at *3; *Kester*, 41 F. Supp. 3d at 330-32. Rather, the *Medco* court observed, a plaintiff need show only “a link” between an AKS violation and a claim to a Federal health care program. 880 F.3d at 98. That is, a plaintiff can prevail by showing “that at least one of [the defendant’s] claims sought reimbursement for medical care that was provided in violation of the Anti-Kickback Statute (as a kickback renders a subsequent claim ineligible for payment).” *Id.*

This conclusion makes sense because the statute does not require this showing, and such a requirement would significantly hamper the government's efforts to prevent healthcare fraud. Indeed, the AKS was enacted in part to eliminate the need for individualized proof of medical decision-making given the inherent difficulties of doing so; instead, kickbacks are presumed to corrupt medical judgments. Moreover, Congress amended the AKS in 2010 "to provide 'a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]'", 880 F.3d at 95 (quoting 42 U.S.C. § 1320a-7b(g)), and thereby to "strengthen whistleblower actions based on medical care kickbacks and to ensure that all claims resulting from illegal kickbacks are considered false claims" for FCA purposes. *Id.* at 96 (quotations omitted); *see also Kester*, 332 F. 3d at 41 ("The legislative history of the 2010 AKS amendment . . . demonstrates that the new provision was intended to do *anything but* narrow existing law) (emphasis added).

Thus, if a pharmaceutical company pays kickbacks to a Medicare patient to induce the patient to purchase the company's drug, and the patient subsequently does so, the resulting claim to Medicare for the drug is false because the medical care was rendered in violation of the AKS. That is so regardless of whether the doctor would have prescribed the drug or the patient would have filled the prescription for the drugs absent the kickbacks. The government insists on compliance with the AKS precisely to ensure it is purchasing the provision of goods and services that are conflict-free and without having to second-guess particular medical decisions. Thus, "[t]he Government does not get what it bargained for when a defendant is paid by [the government] for services tainted by a kickback."

United States ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295, 314 (3d. Cir. 2011).

Accordingly, in this case, Relator Vitale need not prove that federal beneficiaries would not have purchased MiMedx products but for the alleged kickback.

IV. Any Dismissal on FRCP 9(b) Grounds Should be Without Prejudice to the United States

The United States takes no position regarding whether relator has pled his Complaint with sufficient particularity to satisfy FRCP 9(b) and whether the public disclosure bar applies here. The United States requests, however, that if the Court dismisses this action against MiMedx on those grounds, that any such dismissal be without prejudice to the United States. *United States ex rel. Vaughn v. United Biologics, L.L.C.*, Case No. 17-20389, 2018 WL 5000074, at *4 (5th Cir. Oct. 16, 2018) (“because the Government never intervened in the case, and therefore never became a “party” to the litigation, no dismissal as to the Government would be appropriate”); *United States ex rel. Williams v. Bell Helicopter Textron, Inc.*, 417 F. 3d 450, 456 (5th Cir. 2005) (concluding “dismissal with prejudice as to the United States [is] unwarranted where . . . the relator’s claims were dismissed on a Rule 12(b)(6) motion based on lack of specificity in the complaint as required by Rule 9(b)”); *United States ex rel. Rostholder v. Omnicare, Inc.*, Civ. No. CCB-07-1283, 2012 WL 3399789, *15 (D. Md. Aug. 14, 2012).

Pursuant to the False Claims Act, a relator files his or her complaint on behalf of the United States, and once the United States has notified the Court that it declines to pursue relator’s allegations, relator is free to pursue them on his or her own. 31 U.S.C. § 3730.

Under such circumstances, the United States neither files the complaint that initiated the action nor does it serve the complaint on defendants. Because the United States has no part in preparing such complaints, it should not be prejudiced if a relator has failed to plead his or her allegations sufficiently to meet the requirements of FRCP 9(b). Such a result would be unfair because a relator's complaint that is broadly drafted, if dismissed with prejudice as to the United States, could improperly be argued by a defendant to have the preclusive effect of preventing future actions by the United States against the defendants in relator's complaint. This is not in accord with the purpose of the FCA *qui tam* provisions, i.e. assisting the United States in pursuing fraud, not hindering it – and should not be the result of the dismissal of an improperly pleaded complaint by a relator. Moreover, the public disclosure bar does not apply to a claim brought by the United States; a dismissal on that basis therefore is necessarily without prejudice to the United States. Accordingly, the United States submits that, if granted, any dismissal of relator's complaint on these grounds should be without prejudice to the United States.

CONCLUSION

For the foregoing reasons, the United States respectfully asks the Court to reject certain of the Defendant's arguments regarding the viability of an FCA action predicated on a waiver of copays. The United States takes no position on other arguments made by the parties. The United States also asks that, if the Court dismisses the relator's Complaint because it is inadequately plead or runs afoul of the public disclosure bar, it make such dismissal without prejudice to the United States.

Respectfully submitted,

SHERRI A. LYDON
United States Attorney
District of South Carolina

s/ Jennifer Aldrich

Jennifer Aldrich (#06035)
Assistant United States Attorney
District of South Carolina
1441 Main Street, Suite 500
Columbia, SC 29201
(803) 929-3000

JOSEPH H. HUNT
Assistant Attorney General, Civil Division

Michael D. Granston
Jamie Yavelberg
Amy L. Likoff
Attorneys, U. S. Department of Justice
Commercial Litigation Division
P.O. Box 261, Ben Franklin Station
Washington, DC 22044
(202) 305-3713